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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,287	08/27/2003	Jack Saltiel	32001.UT	5496

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EXAMINER
WONG, EDNA

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/649,287	SALTIEL, JACK	
	Examiner	Art Unit	
	Edna Wong	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 18-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-10 and 24-29* is/are allowed.

6)☒ Claim(s) *11-15 and 18-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

This is in response to the Amendment dated September 5, 2006. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Objections

Claims **21-23 and 27-29** have been objected to because of minor informalities.

The rejection of claims 21-23 and 27-29 has been withdrawn in view of Applicant's amendment.

Claim Rejections - 35 USC § 103

Stevens

I. Claims **11-14** have been rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023).

The rejection of claims 11-14 under 35 U.S.C. 103(a) as being unpatentable over Stevens is as applied in the Office Actions dated December 2, 2005 and June 6, 2006 and incorporated herein. The rejection has been maintained for the following reasons:

Applicant states that Applicant believes that while the claim language limits the contents of the reaction mixture to tachysterol, a court would take the view that small, insignificant amounts of other materials may also be present, as long as they do

not materially affect the basic and novel characteristics of the claimed process.

In response, the Examiner deems that 0.001 g/L of anthracene (Stevens, col. 4, lines 53-57) would have been an insignificant amount of an other material that may also be present, and would not have materially affected the basic and novel characteristics of the claimed process.

II. Claim **15** has been rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023) as applied to claims 11-14 above, and further in view of **Michishita et al.** (US Patent No. 6,902,654 B2).

The rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Stevens as applied to claims 11-14 above, and further in view of Michishita et al. is as applied in the Office Actions dated December 2, 2005 and June 6, 2006 and incorporated herein. The rejection has been maintained for the reasons as discussed above.

Applicant's remarks have been fully considered but they are not deemed to be persuasive.

III. Claims **18-22** have been rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023).

The rejection of claims 18-22 under 35 U.S.C. 103(a) as being unpatentable over Stevens is as applied in the Office Actions dated December 2, 2005 and June 6, 2006 and incorporated herein. The rejection has been maintained for the following reasons:

Claim 18, line 2, recites "consisting essentially of".

The phrase "consisting essentially of" limits the scope of a claim to the specified ingredients and those that do not materially affect the basic and novel characteristic of a composition. *Ex parte Davis et al.* 80 USPQ 448 (PTO Bd. App. 1969); *In re Janakirama-Rao* 317 F 2d 951, 137 USPQ 893 (CCPA 1963) - composition; *In re Garnero* 412 F 2d 276, 162 USPQ 221 (CCPA 1969) - article. When Applicant contends that modifying components in the reference composition are excluded by the recitation of "consisting essentially of", Applicant has the burden of showing the basic and novel characteristics of his composition, i.e., a showing that the introduction of these components would materially change the characteristics of Applicant's composition. *In re Lajarte* 337 F 2d 870, 143 USPQ 256 (CCPA 1964).

The Examiner deems that 0.001 g/L of anthracene (Stevens, col. 4, lines 53-57) would have been an insignificant amount of an other material that may also be present, and would not have materially affected the basic and novel characteristics of the claimed process.

IV. Claim **23** has been rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023) as applied to claims 18-22 above, and further in view of **Michishita et al.** (US Patent No. 6,902,654 B2).

The rejection of claim 23 under 35 U.S.C. 103(a) as being unpatentable over Stevens is as applied in the Office Actions dated December 2, 2005 and June 6, 2006

and incorporated herein. The rejection has been maintained for the reasons as discussed above.

Applicant's remarks have been fully considered but they are not deemed to be persuasive.

Malatesta

V. Claims **1-4** have been rejected under 35 U.S.C. 103(a) as being unpatentable over **Malatesta et al.** (US Patent No. 4,388,242).

The rejection of claims 1-4 under 35 U.S.C. 103(a) as being unpatentable over Malatesta et al. has been withdrawn in view of Applicant's remarks.

VI. Claim **5** has been rejected under 35 U.S.C. 103(a) as being unpatentable over **Malatesta et al.** (US Patent No. 4,388,242) as applied to claims 1-4 above, and further in view of **Michishita et al.** (US Patent no. 6,902,654 B2).

The rejection of claim 5 under 35 U.S.C. 103(a) as being unpatentable over Malatesta et al. as applied to claims 1-4 above, and further in view of Michishita et al. has been withdrawn in view of Applicant's remarks.

VII. Claims **6-9** have been rejected under 35 U.S.C. 103(a) as being unpatentable over **Malatesta et al.** (US Patent No. 4,388,242).

The rejection of claims 6-9 under 35 U.S.C. 103(a) as being unpatentable over

Malatesta et al. has been withdrawn in view of Applicant's remarks.

VIII. Claim **10** has been rejected under 35 U.S.C. 103(a) as being unpatentable over **Malatesta et al.** (US Patent No. 4,388,242) as applied to claims 6-9 above, and further in view of **Michishita et al.** (US Patent no. 6,902,654 B2).

The rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Malatesta et al. as applied to claims 6-9 above, and further in view of Michishita et al. has been withdrawn in view of Applicant's remarks.

IX. Claims **11-14** have been rejected under 35 U.S.C. 103(a) as being unpatentable over **Malatesta et al.** (US Patent No. 4,388,242).

The rejection of claims 11-14 under 35 U.S.C. 103(a) as being unpatentable over Malatesta et al. has been withdrawn in view of Applicant's remarks.

X. Claim **15** has been rejected under 35 U.S.C. 103(a) as being unpatentable over **Malatesta et al.** (US Patent No. 4,388,242) as applied to claims 11-14 above, and further in view of **Michishita et al.** (US Patent no. 6,902,654 B2).

The rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Malatesta et al. as applied to claims 11-14 above, and further in view of Michishita et al. has been withdrawn in view of Applicant's remarks.

XI. Claims **24-28** have been rejected under 35 U.S.C. 103(a) as being unpatentable over **Malatesta et al.** (US Patent No. 4,388,242).

The rejection of claims 24-28 under 35 U.S.C. 103(a) as being unpatentable over Malatesta et al. has been withdrawn in view of Applicant's remarks.

XII. Claim **29** has been rejected under 35 U.S.C. 103(a) as being unpatentable over **Malatesta et al.** (US Patent No. 4,388,242) as applied to claims 24-28 above, and further in view of **Michishita et al.** (US Patent no. 6,902,654 B2).

The rejection of claim 29 under 35 U.S.C. 103(a) as being unpatentable over Malatesta et al. as applied to claims 24-28 above, and further in view of Michishita et al. has been withdrawn in view of Applicant's remarks.

Response to Amendment

Claim Objections

Claims **21-23** are objected to because of the following informalities:

Claim 21

line 2, it is suggested that the word "contains" be amended to the words -- consisting essentially of --. See claim 18, line 2.

Claim 22

line 2, it is suggested that the word "contains" be amended to the words --

consisting essentially of --. See claim 18, line 2.

Claim 23

line 2, it is suggested that the word "contains" be amended to the words -- consisting essentially of --. See claim 18, line 2.

Appropriate correction is required.

Allowable Subject Matter

The following is a statement of reasons for the indication of allowable subject matter:

Claims **1-5** define over the prior art of record because the prior art does not teach or suggest a process for the production of previtamin D comprising the steps of a first irradiation and a second irradiation as presently claimed, esp., the step of a second irradiation of said reaction mixture with light energy having a wavelength of approximately 313 nm, the reaction mixture containing no photosensitizer.

Claims **6-10** define over the prior art of record because the prior art does not teach or suggest a process for producing previtamin D comprising the steps of a first irradiation and a second irradiation as presently claimed, esp., the step of a second irradiation of said reaction mixture with light energy having a wavelength of approximately from 300 to less than 330 nm and in the absence of a photosensitizer.

Claims **24-29** define over the prior art of record because the prior art does not teach or suggest a process for the production of vitamin D by light irradiation without the use of a photosensitizer comprising the steps of a first irradiation and a second irradiation as presently claimed.

The prior art does not contain any language that teaches or suggests the above.

Stevens teaches a first stage being irradiation of the selected starting material at 240-265 nm and the second stage being irradiation in the 290-400 nm range in the presence of anthracene (col. 4, lines 32-49).

Malatesta et al. teach a first stage being irradiation of the selected starting material at 245-260 nm and the second stage being irradiation in the 330-350 nm range (col. 1, lines 50-52; col. 2, lines 44-52; and Fig. 1). Applicant has shown that all of the compounds of interest in the process of making vitamin D have zero or near zero absorption of energy above 330 nm (Fig. 8).

Therefore, a person skilled in the art would not have been motivated to adopt the above conditions, and a prima facie case of obviousness cannot be established.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edna Wong whose telephone number is (571) 272-1349. The examiner can normally be reached on Mon-Fri 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Edna Wong
Primary Examiner
Art Unit 1753

EW
October 9, 2006